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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HWANG, VICTOR KENNY

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/941,909

Examiner

Victor K. Hwang

Applicant(s)

BARAK ET AL.

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-42 and 73-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-42 and 73-141 is/are rejected.
- 7) ☒ Claim(s) 29, 85, 112 and 122 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date Aug. 29, 2001.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimers filed on May 5, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of US Patent Numbers 6,478,757 and 6,494,852 have been reviewed and are accepted. The terminal disclaimers have been recorded.

Specification

2. The disclosure is objected to because of the following informalities:
on page 7, line 3, the Brief Description of the Drawings fails to include Figs. 8D and 8E. Appropriate correction is required.

Claim Objections

3. Claims 29, 85, 112 and 122 are objected to because of the following informalities:
in claim 29, the recitation "said sleeve" on line 23 lacks antecedent basis and presumably there is a sleeve that includes the first and second inflatable cells of line 3;
in claim 85, the recitation "said sleeve" on line 1 of page 13 presumably should be changed to --a sleeve--;
in claim 112, the penultimate line, "so as to provide for circumferential constriction," presumably should be removed; and
in claim 122, the recitation "said inflatable cell" on line 3 presumably should be changed to --an inflatable sleeve--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 92, 93, 96-98, 104, 112-116, 118 and 122-125 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ericson* (US Pat. 3,424,151). *Ericson* discloses a device for applying pressure to a body limb having a primary axis, the device comprising an inflatable cell. The inflatable cell includes at least two intra-cell compartments (Fig. 13). Three intra-cell compartments (Figs. 1-9) and four intra-cell compartments (Figs. 10 and 12) are also disclosed. The intra-cell compartments are confluent with each intra-cell compartment being elongated in a direction of the primary axis. Note that elongation increases as the number of intra-cell compartments increases.

The inflatable cell further includes inner and outer shells of durable flexible material with the inner and outer shells bonded together to form a perimetric cell bond. The inner and outer shells are further bonded together, such as at 50, 52 and 53 in the inflatable cell with four intra-cell compartments shown in Figs. 10 and 12. The perimetric cell bond includes upper and lower perimetric cell bonds (see annotations in Fig. 10). The compartmental bonds 50, 52 and 53 are weldments that partly extend between the upper and lower perimetric cell bonds. The compartmental bonds include perforations 60 adjacent the perimetric bond to allow for confluent airflow between adjacent contiguous intra-cell compartments within the cell. The

adjacent intra-cell compartments are spatially fixed relative to each other such that upon inflation, the cell becomes circumferentially constricted.

The inflatable cell has a first center point circumference of $N\pi r$ when the intra-cell compartments are deflated, such as shown in Fig. 7, and a second center point circumference $2N\pi r$ when the intra-cell compartments are inflated, such as shown in Figs. 8, 9, 12 and 13. The second center point circumference is less than the first center point circumference so as to provide circumferential constriction. During inflation, the compartmental bonds are drawn toward each other to decrease a distance therebetween and towards the center point of the intra-cell compartments to decrease a distance therebetween, so as to provide for circumferential constriction.

Since the inflatable cell of *Ericson* is constructed exactly as that of the claimed invention, the inflatable cell of *Ericson* would inherently have a ratio of the second center point circumference to the first point circumference of about 0.64. Applicant's disclosure of this ratio is dimensionless, meaning that it does not depend on any disclosed dimensions of the invention and therefore applies to all devices having the same essential construction as the claimed invention. The inflatable cell disclosed by *Ericson* satisfies this requirement. The center point circumference is decreased upon inflation by about 36%.

The inflatable cell also includes at least one self-operating valve 43 and a fluid inlet 42 to provide for inflation and deflation of the cell.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 29-33, 35, 36, 39-41, 73-75, 78-81, 83-90, 92-95, 97-103, 105, 108-110, 112-116, 118-128, 131-133, 135 and 138-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dye* (US Pat. 5,795,312) in view of *Schneider* (US Pat. 4,206,751) and *Ericson* (US Pat. 3,424,151). *Dye*'312 discloses a device for applying pressure to a body limb having a primary axis. The device is a compression sleeve having first and second inflatable cells 38a-f (three are shown). The inflatable cells are longitudinally adjacent one another and are arranged coaxially with respect to the primary axis of the limb the device is mounted to when in use so that the inflatable cells are intermittently and separately inflated to apply pressure to the limb.

The inflatable cells each comprise inner and outer shells of durable flexible material, the inner and outer shells being bonded together by weldments to form a perimetric cell bond to define the inflatable cell between upper, lower, left and right perimetric cell bonds. Each inflatable cell also comprises at least two longitudinally spaced, confluent intra-cell compartments. The inner and outer shells are further bonded together by weldments to form compartmental bonds within the perimetric cell bond to define the plurality of intra-cell compartments. The compartmental bonds include perforations to allow for confluent air flow

between compartments within a cell. Hook and loop fasteners are mounted to lateral aspects of the inflatable cells so as to form a substantially cylindrical sleeve for secure mounting to the limb.

The compression sleeve is part of a system that includes a sequential compression device (such as those disclosed in US Pats. 4,013,069, 4,030,488, and 4,029,087, see col. 1, lines 30-34) that provides a portable hand-held pump unit for intermittently inflating any one or more selected inflatable cells via a conduit 48. A control means within the sequential compression device is used to determine a treatment specificity of each cell and determines a timing sequence for inflation of each cell based on the determined treatment specificity. The conduit provides a means for the sequential compression device to monitor the air pressure within the various inflatable cells. The conduit may comprise a single tube for delivering fluid to the sleeve (col. 5, lines 25-27).

Dye'312 does not disclose at least three intra-cell compartments being elongated along a primary axis of the body limb and being rectangular in shape when deflated and substantially cylindrical in shape when inflated, the cylindrical axes of the inflated compartments substantially aligning with the primary axis of the limb (claims 29, 36, 73, 75, 83, 85 and 87); at least two intra-cell compartments being elongated in a direction of the primary axis of the limb (claims 92, 97, 105, 112, 122 and 135); the compartmental bonds that define the elongated compartments partly extending between the upper and lower perimetric cell bonds and include perforations to allow for confluent air flow between elongate intra-cell compartments (claims 29, 36, 73, 75, 83, 85, 87, 92, 105, 112 and 135); the sleeve having a center point circumference of $N\pi r$ when the cell is deflated and a center point circumference of

2Nr when the cell is inflated (claims 29, 36, 112, 122 and 135); the sleeve having a first intra-cell compartment center point circumference when the intra-cell compartments are deflated and a second intra-cell compartment center point circumference when the intra-cell compartments are inflated, the second intra-cell compartment center point circumference being less than the first intra-cell compartment circumference so as to provide for circumferential constriction (claims 73, 75, 83, 85, 87, 92, 97 and 105); the compartmental bonds of the elongate intra-cell compartments, during inflation, being drawn towards each other to decrease a distance therebetween and towards the center point of the elongate intra-cell compartments to decrease a distance therebetween, so as to provide for circumferential constriction (claims 29, 36, 73, 75, 83, 85, 87, 92, 97, 105, 112, 122 and 135); the center point circumference is decreased upon inflation by about 36% (claims 30, 113 and 122); perforations located adjacent the perimetric cell bond (claims 33 and 116); and the ratio of the second center point circumference to the first center point circumference is about 0.64 (claims 74, 81, 84, 86, 87, 93 and 98).

Schneider discloses a compression sleeve comprising an inflatable cell 14 including at least three elongate intra-cell compartments separated by compartmental bonds 33 that extend partly between upper and lower perimetric cell bonds and includes perforations to allow confluent air to flow between adjacent intra-cell compartments. The separation of the inflatable cell into elongate intra-cell compartments tends to eliminate movement of the sleeve on a limb which results from ballooning during expansion of the chambers (col. 3, lines 32-38). The intra-cell compartments are substantially cylindrical in shape when inflated with the perforations located adjacent the perimetric bond.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the inflatable cells of *Dye*'312 with the elongated intra-cell compartments of *Schneider*, in order to further eliminate movement of the compression sleeve on the limb which results from ballooning during inflation of the inflatable cell.

Ericson has been discussed above, and such discussion is incorporated herein. *Ericson* also discloses that longitudinal compartments that divide the inflatable cell better resists transverse float of the enclosed limb without undue complication of structure (col. 1, lines 12-41). As previously described, the inflatable cell of *Ericson* is constructed exactly as that of the claimed invention, and as such, the inflatable cell of *Ericson* would inherently have a ratio of the second center point circumference to the first point circumference of about 0.64. Applicant's disclosure of this ratio is dimensionless, meaning that it does not depend on any disclosed dimensions of the invention and therefore applies to all devices having the same essential construction as the claimed invention. The inflatable cell disclosed by *Ericson* satisfies this requirement. The center point circumference is decreased upon inflation by about 36%.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made that the inflatable cells of *Dye*'312 and *Schneider* take the construction of the inflatable cell of *Ericson*, since such construction is well known in the art and since *Ericson* also teaches that the use of longitudinal intra-cell compartments better resists transverse floating of the sleeve on a limb without undue complication of the structure.

8. Claims 34, 42, 82, 91, 96, 104, 111, 117 and 134 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dye* (US Pat. 5,795,312) as modified by *Schneider* (US Pat. 4,206,751) and *Ericson* (US Pat. 3,424,151) as applied to claims 29, 36, 75, 87, 92, 97, 105, 112 and 128 above, and further in view of *Dye et al.* (US Pat. 4,029,087). *Dye*'312 as modified by *Schneider* and *Ericson* discloses the invention as claimed except for the perforations are located between compartmental bonds extending from the upper and lower perimetric bonds (claims 34 and 117); and the sleeve comprising at least one self-operated valve (claims 42, 82, 91, 96, 104, 111 and 134).

Dye et al. '087 discloses a compression sleeve and various means for providing an inflatable cell with multiple confluent intra-cell compartments (Figs. 6-12). Figs. 10-12 show intra-cell compartments formed by compartment bonds partly extending between perimetric cell bonds wherein the compartment bonds include perforations to allow for confluent air flow between compartments in the inflatable cell. The perforations may be located adjacent the perimetric cell bond or they may be equivalently be located between compartmental bonds extending from the perimetric bonds.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the inflatable cells of *Dye*'312 as modified by *Schneider* and *Ericson* with perforations between compartmental bonds extending from the upper and lower perimetric bonds, since *Dye et al.* '087 shows that locating perforations adjacent to the perimetric bonds is equivalent to locating the perforations between compartmental bonds extending from the perimetric bonds.

Dye et al. '087 also discloses use of at least one self-operated valve 38 and 58 on the compression sleeve for providing sequential inflation of the inflatable chambers in the treatment of a user's limb. These valves are necessary when the conduit comprises a single tube for delivering fluid to the sleeve, as disclosed by *Dye* '312.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the compression sleeve of *Dye* '312 as modified by *Schneider* and *Ericson* with the at least one self-operated valves of *Dye et al.* '087, since such valves allow for sequential inflation of the inflatable cells when the conduit comprises a single tube for delivering fluid to the sleeve, an embodiment disclosed by *Dye* '312.

9. Claims 37, 38, 76, 77, 106, 107, 136 and 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Dye* (US Pat. 5,795,312) as modified by *Schneider* (US Pat. 4,206,751) and *Ericson* (US Pat. 3,424,151) as applied to claims 36, 75, 105 and 135 above, and further in view of *Cariapa et al.* (US Pat. 5,891,065). *Dye* '312 as modified by *Schneider* and *Ericson* discloses the invention as claimed except for the pump unit being battery operated (claims 37, 76, 106 and 136); and the battery being a rechargeable battery (claims 38, 77, 107 and 137).

Cariapa et al. discloses a portable pump unit for a compression sleeve being operated by a rechargeable battery 164.1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the sequential compression device of *Dye* '312 as modified by *Schneider* and *Ericson* with the rechargeable battery of *Cariapa et al.*,

in order to provide added portability convenience so that use does not require an electrical outlet.

10. Claim 141 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Dye* (US Pat. 5,795,312) as modified by *Schneider* (US Pat. 4,206,751), *Ericson* (US Pat. 3,424,151) and *Cariapa et al.* (US Pat. 5,891,065) as applied to claim 136 above, and further in view of *Dye et al.* (US Pat. 4,029,087). *Dye*'312 as modified by *Schneider*, *Ericson* and *Cariapa et al.* discloses the invention as claimed except for the sleeve comprising at least one self-operated valve.

Dye et al. '087 has been discussed above, and such discussion is incorporated herein. *Dye et al.* '087 discloses use of at least one self-operated valve 38 and 58 on the compression sleeve for providing sequential inflation of the inflatable chambers in the treatment of a user's limb. These valves are necessary when the conduit comprises a single tube for delivering fluid to the sleeve, as disclosed by *Dye*'312.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the compression sleeve of *Dye*'312 as modified by *Schneider*, *Ericson* and *Cariapa et al.* with the at least one self-operated valves of *Dye et al.* '087, since such valves allow for sequential inflation of the inflatable cells when the conduit comprises a single tube for delivering fluid to the sleeve, an embodiment disclosed by *Dye*'312..

Response to Arguments

11. Applicant's arguments with respect to claims 29-42 and 73-141 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Van Court et al. (US Pat. 2,823,668), *Nicoll* (US Pat. 3,164,152), *Bailey et al.* (US Pat. 3,186,405), *Clarey* (US Pat. 4,157,713), *Graziano* (US Pat. 4,266,298), *Curlee* (US Pat. 4,682,587), *Curlee* (US Pat. 4,682,588), *Sebastian* (US Pat. 5,728,055), *Arkans* (US Pat. 6,007,559) and *Kloecker* (US Pat. 6,315,745 B1) disclose various reasons for providing inflatable sleeves having inflatable chambers divided into multiple elongate longitudinal intra-cell compartments. Reasons include constriction, better and more comfortable fit, equivalence to fully encircling inflatable cells, uniform application of pressure, and ventilation.

Dye (US Pat. 5,186,163) discloses a compression device comprising multiple inflatable cells selectively inflated and controlled by a pump unit having a control unit.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor K. Hwang whose telephone number is (703) 308-2865. The examiner can normally be reached Monday through Friday from 7:30 AM to 4:00 PM Eastern time. The facsimile number for submitting papers directly to the examiner for informal correspondence is (703) 746-4891. The facsimile number for submitting all formal correspondence is (703) 872-9306.

Any Inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 3700 receptionist at (703) 308-0858.



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Victor K. Hwang
March 10, 2004